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ENCLOSURES (Check all that apply)

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APPEAL
Serial No.: 09/739,357
Docket# US000436

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

In re the Application of

Inventors : Craig S. Aman
Application No. : 09/739,357
Filed : December 19, 2000
For : WEB ENABLED MEDICAL DEVICE TRAINING

APPEAL BRIEF

On Appeal from Group Art Unit 3714

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I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands, successor by assignment from the original assignee, Agilent Technologies.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-25 and 38-47 are pending in the application. Claims 1-25 and 38-47 stand twice rejected. Claims 26-37 and 48-49 have been canceled. The claims being appealed are Claims 1-13 and 38-45.

IV. STATUS OF AMENDMENTS

No amendment was filed in response to the most recent Office action mailed May 11, 2005. This Office action was issued in response to a request for continued examination and subsequent entry of an Amendment After Final Action filed February 14, 2005.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The subject matter of the claimed invention as per Claims 1, 38, and their dependent claims is a method for providing instruction on the use of a medical device to a user computer. The inventive method may be carried out by a server computer 102 which communicates over a network 104 to a trainee computer 106 (Claims 1 and

38: "user computer") as shown in Fig. 1 and described on page 5, lines 13-25. The method begins in the illustrated example with a request for instruction on use of a medical device from the trainee computer 106 (Claim 1a) running a medical device training program 202 as described at column 7, lines 18-25. In the illustrated example the medical device is an automated external defibrillator. The request causes a series of operational steps to be performed by the server 102. The server responds by providing a list 502 of instructional topics associated with the defibrillator (Claim 1b). This list is displayed on the graphical user interface of the trainee computer 106 as shown by the training topic screen in the constructed embodiment of Fig. 5 and discussed on page 9, lines 13-21. As explained in this passage, selecting an item on the list 502 will cause a related list 602 of instructional subtopics to appear on the graphical user interface (Claim 1c). Such a subtopic screen display 600 is shown in Fig. 6 and is easily accessed in this embodiment because topics on the first list are constructed as links. The subtopic screen display 600 is described on page 8, line 23 through page 9, line 9. When the trainee user selects one of the instructional subtopics 602 a plurality of instructional graphical user interface screens 700-1100 pertaining to the subtopic are presented (Claim 1d). These screens provide simulated, hands-on operation of the defibrillator through interactive simulation objects which simulate operating controls (Claim 1d; Claim 38a) or first aid objects (Claim 38b) of the defibrillator. For instance, Fig. 8 displays medical device first aid instrument objects of the defibrillator, simulated electrode pads 820, which the trainee user is asked to place on the chest of the simulated patient. The user selects the pads 820 on the screen and manipulates them (Claim 38g) to place and position the pads in the proper locations on the patient's chest as described on page 9, lines 25-29. The trainee

user can also click on the "AUDIO" icon to hear the actual audio instructions played by the defibrillator during its use as described on page 10, lines 14-15 and page 10, line 24 through page 11, line 13. The user can observe a live video of the ECG trace as shown in Fig. 9 and, if a shock is advised, can press a medical device control object of the defibrillator, the simulated orange shock button 1024, as shown in Fig. 10. For each simulation, interaction feedback is provided (Claim 1e; Claim 38c) to assess the trainee user's competence in operating the defibrillator controls and performing first aid techniques with the defibrillator. The feedback indicates to a trainee user whether a simulation interaction is appropriate under the given conditions of the simulation (Claim 1e), as well as the correctness of the user interaction with the defibrillator (Claim 1e; Claim 38c) as described on page 8, lines 4-13.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether Claims 1-13 and 44-45 stand correctly rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hon (U.S. Pat. 6,074,213) in view of Ramshaw et al. (U.S. Pat. 5,791,907), Linberg (U.S. Pat. 6,386,882), Parker et al. (U.S. Pat. 6,321,113) and Olson et al. (U.S. 5,645,571).

2. Whether Claims 38-43 stand correctly rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Hon in view of Linberg and Parker et al.

VII. ARGUMENT

A. Rejection of Claims 1-13 and 44-45 as unpatentable over Hon, Ramshaw et al., Linberg, Parker et al. and Olson et al.

Claims 1, 4, 5, 7-10, 12-13 and 44-45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hon in view of Ramshaw et al. and Linberg. Claims 2, 6, and 11 were rejected by adding Parker et al. to this combination of patents. Claim 3 was rejected with the further addition of Olson et al.

The Hon patent describes a system for enabling a medical or surgical team to train in treating a single patient together while at separate locations. The keys to making this possible are the use of a computer network to provide a “virtual patient” which each individual can see on a computer screen (*e.g.*, 40,41,42) at his/her location, and “psychomotor inputs” by which each participant can carry out his/her part of the medical procedure, including the physical devices shown in Figs. 6-8; and a computer which responds to inputs from the psychomotor devices to develop responses of the virtual patient. The team members participate in the procedure by squeezing, moving, or otherwise manipulating the psychomotor devices. The physical psychomotor devices are connected to the computers of the team members so that their physical manipulation can be sensed and the effects of the actions used in the patient display. It is seen that Hon does not instruct the use of a medical device, he enables remotely located team members to practice a medical procedure together. There is no list of instructional topics on a display screen, the selection of which displays a list of related subtopics for instruction. Medical device control objects and medical device first aid instrument objects are not provided in a graphical user interface, they are provided as the tangible psychomotor devices shown for instance in Figs. 6-8 of Hon. The computer screens in Hon are used to depict the virtual patient to each participant. This means that there cannot be participant interaction with medical device control objects and medical device first aid instrument objects on a

graphical user interface. Furthermore, there is no feedback indicating the correctness of such interaction. Instead, the results of the use of the psychomotor devices with the virtual patient and with each other is simply presented by the Hon computer. Whether this interaction is correct or appropriate is left to the team members to decide. Since the psychomotor devices are not meant to simulate actual medical devices but only to provide the effects of use of actual medical devices, the Hon system assumes that the participants in a training exercise are already skilled in the use of those medical devices, whereas an embodiment of the present invention may be designed to instruct basic, novice users on the use of a medical device such as a defibrillator. It is seen that there are numerous deficiencies compared to the elements of Claim 1.

To provide these deficiencies the Examiner first cites Ramshaw et al. Ramshaw et al. describe an interactive surgery training video system. The video system can be used in various ways which are discussed in the example of part III of the patent beginning in column 13 at line 15. One option is to view references associated with a particular procedure. Another option is to take a quiz on a procedure. Another option is to observe surgery by watching a video. An interactive option is the "instrument option" which prompts the user to select the next surgical instrument to be used between fragments of video. See column 14 at lines 6-14. The user begins by selecting a particular surgical procedure. When this is done the display shows the list of steps of the procedure and the user is able to go through the entire procedure or pick only a selected step or steps. The interactive selection of instruments shows the user a list of instruments from which the user is to select the proper instrument for the next step in the procedure. As described in columns 15 and 16, a scalpel or a finger are to be selected for the steps described in the example. If

the user picks an incorrect instrument the user is given a hint in the form of a description of the action to be performed, such as "make an incision" or "dissect the preperitoneal space with a finger." If the user picks incorrectly the hint is repeated as described in column 16. When the user selects the proper instrument the video plays to show how the instrument is used in the next step in the procedure. While the list of steps in the procedure may be viewed as subtopics of the topic of the selected procedure, there is no interactive manipulation of a simulated instrument. The user in Ramshaw et al. is simply given a multiple choice quiz which asks the user to pick the next instrument to use and is given a hint if a wrong choice is made until the proper choice is made. The system then plays the video showing how an expert physician uses the instrument. Since the user does not manipulate or otherwise interact with a displayed simulated instrument it follows that there is no feedback on whether a particular interaction with a simulated object is appropriate or whether the user used the instrument correctly.

Linberg describes a remotely delivered training system for operators of software applications for monitoring patient data. The operator issues a request to be trained on a particular software application. The computer at the remote location selects the appropriate training module and delivers it to the operator's local computer. The operator then executes the skill-based training activity. A typical activity is to complete a fifty question test as described in column 18, lines 52-55. The test is then graded and, if the operator achieves a desired test score, the operator is certified at a particular operator skill level. The certification is sent to a certification authority and the operator is granted access to use the specific software application through an authorization key. Linberg has the same deficiencies as Hon. There is no list of

instructional topics keyed to corresponding sub-topics, no interactive simulation objects of a medical device for the operator to manipulate on a screen, and no feedback on interaction with an interactive simulation object which tells whether a particular interaction is appropriate under the circumstances or whether the interaction was correctly used on a medical device.

Parker et al. describes a system for downloading event data from an AED to a rescue scene computer which can be transported back to a medical facility for analysis. As shown in Fig. 8, the system is capable of analyzing the downloaded event data and evaluating the performance of the AED and the AED operator during the rescue. The only mention of training or instruction is with regard to Fig. 12, where a record of training taken by an operator can be recorded. Parker et al. lacks virtually all of the claim elements of the present invention except for the involvement of a defibrillator and a computer with a display screen.

Finally, Olson et al. describes an AED with a self-test feature. The paragraph spanning columns 6-7 describes the functions which are tested by the self-test procedure. At the bottom of column 7 is a description of the event data that can be stored by the AED. Like Parker et al, Olson et al. lacks virtually all of the claim elements of the present invention except for a medical device, an AED, and a display panel. It is of the same relevance as Parker et al.

From the foregoing analysis and the listing of missing claim elements it is respectfully submitted that this group of patents in the aggregate cannot render Claim 1 or its dependent Claims 2-13 and 44-45 unpatentable.

B. Rejection of Claims 38-43 as unpatentable over Hon in view of Linberg and Parker et al.

Claim 38 describes a method for providing instruction on the use of a medical device to a user computer, the method comprising providing a medical device control object in a first graphical user interface, the medical device control object simulating a control of the medical device; providing a medical device first aid instrument object in the first graphical user interface or a second graphical user interface, the medical device first aid object simulating a first aid component of the medical device; allowing a trainee to interact with the medical device control object and medical device first aid instrument object by manipulation of the displayed medical device control object and medical device first aid instrument object in the first or second graphical user interface; and providing feedback in response to interacting with the medical device control object and medical device first aid instrument object, the feedback indicating the correctness of the interaction with the medical device control object and the medical device first aid instrument object. From the foregoing analysis of Hon, it is seen that this patent does not provide a medical device control object in a graphical user interface which simulates a medical device control and a medical device first aid instrument object in a graphical user interface which simulates a first aid component of the medical device. Hon uses physical psychomotor devices connected to computers. Furthermore Hon does not show or suggest a system enabling a trainee to interact with a simulated medical device control object or a simulated first aid instrument by manipulating them on the display. It follows that the Hon system provides no feedback on the correctness of the interaction since there is no manipulative interaction of displayed control objects or instruments in Hon. Linberg, as explained above, describes a remotely delivered training module for training and certifying programmers of software applications. It lacks all of the claim

elements lacking in Hon. Parker et al., as explained above, is concerned with downloading event data and can analyze event data to evaluate the effectiveness of the performance of an AED and its operator as indicated by that data, and can store an operator training record. Parker et al. adds none of the claim elements missing from Hon and Linberg. It is therefore respectfully submitted that Claim 38 and its dependent Claims 39-43 are patentable over the combination of Hon, Linberg, and Parker et al.

Respectfully submitted,

CRAIG S. AMAN

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CLAIMS APPENDIX

- 1) (Previously presented) A method for providing instruction on the use of a medical device to a user computer, the method comprising:
 - a) receiving a request for instruction on the use of the medical device over a network, the request originating from the user computer;
 - b) providing a first graphical user interface having a list of instructional topics associated with the medical device to the user computer in response to the request;
 - c) providing a second graphical user interface having a list of instructional sub-topics associated with an item on the list of instructional topics to the user computer in response to receiving a request for the item on the list of instructional topics from the user computer;
 - d) providing a plurality of instructional graphical user interfaces having instructions pertaining to an item on the list of instructional sub-topics to the user computer in response to receiving a request for the item on the list of the instructional sub-topics from the user computer, at least one of the first, second and plurality of instructional graphical user interfaces including at least one interactive simulation object with which interaction simulates operating controls or device instruments of the medical device; and
 - e) generating a feedback in response to interacting with the interactive simulation object indicating (i) whether a particular interaction is appropriate under given conditions; and (ii) the correctness on the use of the medical device.
- 2) (Original) The method according to claim 1, wherein the medical device is an Automatic External Defibrillator (AED).
- 3) (Original) The method according to claim 1, wherein the list of instructional topics include at least a utility of the medical device item, an operation of the

medical device item, a device troubleshooting item and a device maintenance item.

- 4) (Original) The method according to claim 1, further comprising:
 - a) providing an audio in at least one of the graphical user interfaces.
- 5) (Original) The method according to claim 1, further comprising:
 - a) providing linear and non-linear navigation from at least one of the graphical user interfaces to another of the graphical user interfaces.
- 6) (Original) The method according to claim 1, wherein the instructional information in each of the plurality of instructional graphical user interface includes a text description of one or more operational steps pertaining to the selected item on the list of instructional sub-topics.
- 7) (Original) The method according to claim 6, further comprising:
 - a) providing in one or more of the plurality of instructional graphical user interfaces one or more still images illustrating the text description of the one or more operational steps.
- 8) (Original) The method according to claim 6, further comprising:
 - a) providing in one or more of the plurality of instructional graphical user interfaces an interactive animation illustrating the text description of the one or more operational steps.
- 9) (Original) The method according to claim 6, further comprising:
 - a) providing in one or more of the plurality of instructional graphical user interfaces a video illustrating the text description.
- 10) (Original) The method according to claim 6, wherein each of the plurality of instructional graphical user interfaces is provided based on the order in which the

one or more operational steps in the text description would be performed during the proper operation of the device.

- 11) (Original) The method according to claim 10, wherein the medical device is an Automatic External Defibrillator (AED).
- 12) (Original) The method according to claim 10, further comprising:
- a) providing in one or more of the plurality of instructional graphical user interfaces an interactive animation illustrating the text description of the one or more operational steps.
- 13) (Original) The method according to claim 12, wherein user interaction is required for the animation illustrating the text description of the one or more operational steps.
- 14) (Previously presented; **not on appeal**) A system for providing instruction on the use of a medical device, the system comprising:
- a) a network;
 - b) a user computer coupled to the network for requesting instructional information on the use of the medical device; and
 - c) a server coupled to the network;
- wherein the server provides a first graphical user interface having a list of instructional topics associated with the medical device to the user computer in response to the request for instruction, provides a second graphical user interface having a list of instructional sub-topics associated with an item on the list of instructional topics to the user computer in response to receiving a request for the item on the list of instructional topics from the user computer, provides a plurality of instructional graphical user interfaces having instructional information pertaining to an item on the list of instructional sub-topics to the user computer in response to receiving a request for the item on the list of the instructional sub-topics from the user computer, at least one of the first, second, and plurality of instructional graphical user interfaces including at least one interactive simulation

object with which interaction simulates operating controls or device instruments of the medical devices, and generates a feedback in response to interacting with the interactive simulation object indicating (i) whether a particular interaction is appropriate under given conditions; and (ii) the correctness on the use of the medical device.

15) (Original; **not on appeal**) The system according to claim 14, wherein the medical device is an Automatic External Defibrillator (AED).

16) (Original; **not on appeal**) The system according to claim 14, wherein the network is the Internet or an Intranet.

17) (Original; **not on appeal**) The system according to claim 14, wherein the list of instructional topics include at least a utility of the medical device item, an operation of the medical device item, a device troubleshooting item and device maintenance item.

18) (Original; **not on appeal**) The system according to claim 14, further comprising:
a) an audio object provided in at least one of the graphical user interfaces permitting the user to listen to an audio.

19) (Original; **not on appeal**) The system according to claim 14, further comprising:
a) a linear navigation object and a non-linear navigation object provided in at least one of the graphical user interfaces permitting the user to navigate from the at least one of the graphical user interface displays to another of the graphical user interfaces.

20) (Original; **not on appeal**) The system according to claim 14, wherein the instructional information includes a text description of one or more operational steps pertaining to the selected item on the list of instructional sub-topics.

21) (Original; **not on appeal**) The system according to claim 20, further comprising:

- a) at least one still image object provided in each of the plurality of instructional graphical user interfaces for illustrating the text description of the one or more operational steps.

22) (Original; **not on appeal**) The system according to claim 20, further comprising:

- a) an interactive animation object provided in the at least one instructional graphical user interfaces for illustrating the text description of the one or more operational steps.

23) (Original; **not on appeal**) The system according to claim 20, further comprising:

- a) a video object provided in at least one of the plurality of instructional graphical user interfaces for illustrating the text description of the at least one instructional graphical display.

24) (Original; **not on appeal**) The system according to claim 20, wherein each of the plurality of instructional graphical user interfaces is provided based on the order in which the one or more operational steps in the text description would be performed during the proper operation of the device.

25) (Original; **not on appeal**) The system according to claim 24, wherein the medical device is an Automatic External Defibrillator (AED).

26) -37)(Cancelled)

38) (Previously presented) A method for providing instruction on the use of a medical device to a user computer, the method comprising:

- a) providing a medical device control object in a first graphical user interface, the medical device control object simulating a control of the medical device;
- b) providing a medical device first aid instrument object in the first graphical user interface or a second graphical user interface, the medical device first aid object simulating a first aid component of the medical device;

- g) allowing a trainee to interact with the medical device control object and medical device first aid instrument object by manipulation of the displayed medical device control object and medical device first aid instrument object in the first or second graphical user interface; and
- c) providing feedback in response to interacting with the medical device control object and medical device first aid instrument object, the feedback indicating the correctness of the interaction with the medical device control object and the medical device first aid instrument object.

39) (Original) The method according to claim 38, wherein the medical device is an Automatic External Defibrillator (AED).

40) (Original) The method according to claim 38, further comprising:

- d) providing an audio, the audio disclosing instructional information related to the medical device.

41) (Previously presented) The method according to claim 38, further comprising:

- e) providing text description of one or more operational steps pertaining to the medical device.

42) (Previously presented) The method according to claim 41, further comprising:

- f) providing one or more still images illustrating the concept disclosed by the text description of the one or more operational steps.

43) (Previously presented) The method according to claim 41, further comprising: providing a video illustrating the concept disclosed by the text description of the one or more operational steps.

44) (Previously presented) The method according to claim 1 wherein the interactive simulation object comprises a medical device control object.

45) (Previously presented) The method according to claim 1 wherein the interactive simulation object comprises a medical device first aid instrument object.

46) (Previously presented; **not on appeal**) The method according to claim 14 wherein the interactive simulation object comprises a medical device control object.

47) (Previously presented; **not on appeal**) The method according to claim 14 wherein the interactive simulation object comprises a medical device first aid instrument object.

48) (Canceled)

49) (Canceled)

EVIDENCE APPENDIX

None. No extrinsic evidence has been submitted by either party in this case.

RELATED PROCEEDINGS APPENDIX

None. There are no related appeals or interferences.